

PSJ3

Exhibit 24

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From: Rosen, Burt
Sent: Sun 2/15/2004 8:19:32 AM
Subject: FW: DEA hydrocodone to C-II?

interesting story that shows the complex and difficult problems between patients and abuse. this is what we have always said. hydrocodones are the largest, number one generic prescription in the US. 100 Million Rx's a year. we are all part of a bigger problem of prescription drug abuse.

U.S. Is Working to Make Painkillers Harder to Obtain

Patients May Suffer as DEA Battles Abuse

By Marc Kaufman
Washington Post Staff Writer
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The Drug Enforcement Administration is working to make one of the nation's most widely prescribed medications more difficult for patients to obtain as part of its stepped-up offensive against the diversion and abuse of prescription painkillers.

Top DEA officials confirm that the agency is eager to change the official listing of the narcotic hydrocodone -- which was prescribed more than 100 million times last year -- to the highly restricted Schedule II category of the Controlled Substances Act. A painkiller and cough suppressant sold as Lortab, Vicodin and 200 generic brands, hydrocodone combined with other medications has long been available under the less stringent rules of Schedule III.

The DEA effort is part of a broad campaign to address the problem of prescription drug abuse, which the agency says is growing quickly around the nation. But the initiative has repeatedly pitted the agency against doctors, pharmacists and pain sufferers, and it is doing so again with the hydrocodone proposal.

Pain specialists and pharmacy representatives say that the new restrictions would be a burden on the millions of Americans who need the drug to treat serious pain from arthritis, AIDS, cancer and chronic injuries, and that many sufferers are likely to be prescribed other, less effective drugs as a result.

If the change is made, millions of patients, doctors and pharmacists will be affected, some substantially. Patients, for instance, would have to visit their doctors more often for hydrocodone prescriptions, because they could not be refilled; doctors could no longer phone in prescriptions; and pharmacists would have to fill out significantly more paperwork and keep the drugs in a safe. Improper prescribing would carry potentially greater penalties.

The DEA says the change is necessary because hydrocodone is being widely misused -- with a 48 percent increase in emergency room reports of hydrocodone abuse from 1998 to 2001. The drug, a semisynthetic chemical cousin of opium, produces a morphine-like euphoria if taken without a medical purpose but generally does not produce a similar "high" in patients with severe or chronic pain. Hydrocodone was one of several prescription painkillers that radio talk show host Rush Limbaugh acknowledged last year that he was addicted to.

"Hydrocodone is one of the most abused drugs in the nation," said Christine Sannerud, deputy chief of the drug and chemical evaluation section of the DEA. "The agency thinks it would be wise to move it to Schedule II, because that would help a lot in terms of reducing abuse and trafficking."

DEA officials would not say when they might begin the process of changing the schedule, but other federal officials said they understand that the DEA wants to act soon.

Under the federal Controlled Substances Act of 1970, the DEA places all narcotic or mind-altering drugs into one of five "schedules," and the medications are more or less available based on the potential dangers they pose and benefits they provide. Morphine-based hydrocodone, when combined with aspirin, acetaminophen or other common analgesics, has been a Schedule III drug since the act went into effect.

The DEA effort comes as the agency is already embroiled in a dispute with many pain specialists over the use -- and alleged overprescribing -- of another powerful painkiller, OxyContin. Scores of doctors have been arrested on felony charges of conspiracy, drug trafficking and even murder in connection with their prescribing.

Although the agency says the prosecutions are needed to shut down "pill mills" and stop unscrupulous doctors, many pain specialists say that the agency has become overzealous and that some doctors are refusing to prescribe needed painkillers because they fear DEA investigation.

"Rescheduling the drug will bring more hoops and barriers to getting access to the drugs, and it may prevent some minimal amount of abuse," said Richard Payne, president of the American Pain Society. "But my concern is that it will come at the cost of denying access to thousands of patients."

Susan Winkler of the American Pharmacists Association said her organization is concerned that the "ripple effects" would be substantial and negative.

"Our members and doctors would have increased liability if [hydrocodones] are rescheduled, and that will inevitably reduce prescribing," she said. "We urge the DEA to make sure their decision is based on science and will make the situation better, not worse."

Reflecting the complexity of the issue, the Florida legislature tightened rules on hydrocodone in 2000. At the request of state enforcement officials, lawmakers made the same change that the DEA wants. But in 2001, after patients and health care providers protested loudly, Florida repealed it.

The process of changing the classification of a controlled drug is cumbersome and time-consuming and involves a formal review by the Food and Drug Administration, a listing in the Federal Register and a public comment period. The DEA, however, has the final authority.

The DEA's Sannerud said hydrocodones have become an increasing problem as the number of Americans taking the drug skyrockets. According to statistics from IMS Health, which collects information about prescription drugs, the number of hydrocodone prescriptions rose from about 80 million in 1999 to 100 million in 2002. That is about four times as many prescriptions as are written annually for oxycodone, the active narcotic in the high-profile drug OxyContin.

Hydrocodone has been made for decades but, because most brands are less profitable off-patent drugs, it is generally not heavily marketed. Two generic versions, distributed by Tyco Healthcare/Mallinckrodt and Watson Pharmaceuticals Inc., were listed by IMS Health as the third and sixth most prescribed drugs in the nation last year.

Sannerud said the DEA has contacted several companies that make hydrocodone and not heard any strong opposition to a schedule change. Several of the larger manufacturers, however, said in interviews they were not aware of DEA's plans.

Sannerud said her agency took up the issue because of a citizen's petition filed by a doctor in upstate New York, Ronald Dougherty.

The doctor, who runs an inpatient drug recovery center outside Syracuse, said he had sent letters for years urging the rescheduling annually.

"With all the focus on OxyContin, the abuse of hydrocodones has been very underappreciated," said Dougherty, who remarked that almost a quarter of his patients are addicted to it.

Charles Cichon, president of the National Association of Drug Diversion Investigators Inc., representing both law enforcement and prosecutors, said his group has urged rescheduling for years.

"This is widely accepted to be the nation's most abused prescription drug, and a big reason why is that it's Schedule III and can be called in by a doctor," he said. "That opens the door to a lot of abuse."

But John T. Farrar, a pain specialist at the University of Pennsylvania and a consultant to the FDA advisory panel on analgesics, said taking away a doctor's ability to call in a hydrocodone prescription would have serious consequences for patient care.

"There's really no substitute that doctors would be allowed to call in," Farrar said. "That means many patients would probably be getting other Schedule III drugs that are less effective for their pain, while drug abusers will just find another source."